UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
EASTERN DIVISION

ELIZABETH MORGAN TODD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**CIVIL ACTION NUMBER:**
	)	
PFIZER, INC., a corporation; FICTITIOUS DEFENDANTS A–Z, whose names are Unknown to the Plaintiff at this time and whose involvement are detailed herein,	)	**1:18-cv-01513-LSC**
	)	
Defendants.	)	

DEFENDANT PFIZER INC.'S MOTION TO DISMISS PLAINTIFF'S FIRST AMENDED COMPLAINT AND MEMORANDUM IN SUPPORT

Defendant Pfizer Inc. moves to dismiss Plaintiff's First Amended Complaint (FAC) for failure to state a claim upon which relief can be granted. As explained below, the FAC cures none of the pleading deficiencies that this Court identified in dismissing the original Complaint. *See* Doc. 17. Accordingly, this Court should dismiss the FAC with prejudice.

BACKGROUND

Plaintiff Elizabeth Morgan Todd alleges that she was prescribed Lyrica to treat her fibromyalgia "in or around August 2008." Doc. 18, ¶¶ 13, 76. She alleges that she used Lyrica "for years" and "suffered severe adverse reaction[s]," including "permanent memory loss" and "cognitive decline." Doc. 18, ¶ 22. On September

17, 2018, more than a decade after she was allegedly first prescribed Lyrica, Plaintiff filed her original Complaint, asserting claims for (1) negligence; (2) violations of the Alabama Extended Manufacturers' Liability Doctrine (AEMLD); (3) breach of express warranty; (4) breach of implied warranties; (5) fraudulent misrepresentation; (6) fraudulent concealment; (7) negligent misrepresentation; (8) fraud and deceit; (9) violation of consumer protection laws; (10) negligence – failure to warn; and (11) negligence – negligent design.

On May 29, 2019, this Court dismissed Plaintiff's warnings- and design-based claims as preempted by federal law. Doc. 17, at 5−8. And the remainder of her claims, this Court found, failed to meet the basic pleading requirements. *Id.* at 8−10. The Court thus dismissed all of Plaintiff's claims while permitting Plaintiff to re-plead her claims. *Id.* at 10−11.

Plaintiff's FAC fares no better than her first pleading. It cures none of the problems that led to the dismissal of the original Complaint. The FAC still does not plausibly allege that Pfizer had "newly acquired information" after FDA approval and before Plaintiff's alleged injury that would have allowed it to use FDA's "Changes Being Effected" (CBE) regulation to change the label.[1] Nor does (or can)

[1] As this Court has explained, "'a manufacturer may [generally] only change a drug label after the FDA approves a supplemental application,' . . . manufacturers of name brand drugs may in certain instances make unilateral changes to the label of its drug under the [CBE] regulation" if there is "newly acquired information." Doc. 17, at 5–6 (quoting *Wyeth v. Levine*, 555 U.S. 555, 568 (2009); 21 C.F.R. § 314.70(c)(6)(iii)(A)); *see also, e.g.*, *McGee v. Boehringer Ingelheim Pharms.*,

the FAC plausibly allege a non-preempted design-defect claim. And Plaintiff's fraud, warranty, and consumer protection claims remain as conclusory now as they were in the original and deficient Complaint.

Accordingly, this Court should dismiss the FAC with prejudice in its entirety.

LEGAL STANDARD

"To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). To be plausible on its face, the complaint must "contain[] sufficient facts to support a reasonable inference that the defendant is liable for the misconduct alleged." *Gates v. Khokhar*, 884 F.3d 1290, 1296 (11th Cir. 2018). Plausibility requires allegations showing more than a "sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678. "This necessarily requires that a plaintiff include factual allegations for each essential element of his or her claim." *GeorgiaCarry.Org, Inc. v. Georgia*, 687 F.3d 1244, 1254 (11th Cir. 2012). "'Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements,' and 'unadorned, the-defendant-unlawfully-harmed-me

Inc., No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *3 (N.D. Ala. Mar. 20, 2018); *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41–42 (1st Cir. 2015).

accusation[s],' cannot withstand a motion to dismiss." *Odion v. Google Inc.*, 628 F. App'x 635, 637 (11th Cir. 2015) (quoting *Iqbal*, 556 U.S. at 678).

ARGUMENT

I. Federal law preempts Plaintiff's AEMLD, negligent failure-to-warn and design-defect claims.

This Court held that Plaintiff's negligent failure-to-warn, AEMLD, and design-defect claims, as pled in the initial Complaint, are preempted by federal law. Doc. 17, at 5−8. Those claims should again be dismissed because the FAC fails to cure the deficiencies that this Court specifically identified.

A. Federal law preempts Plaintiff's failure-to-warn claims.

Plaintiff's FAC still does not plausibly allege a failure-to-warn claim that survives preemption. In dismissing Plaintiff's original failure-to-warn claims, this Court explained that the Complaint "d[id] not contain sufficient *factual allegations* to plausibly indicate that newly acquired information became available to Pfizer such that Pfizer could or should have changed their warning label through the CBE process." Doc. 17, at 6 (emphasis added). That is still the case.

In the original Complaint, Plaintiff referenced two unnamed and uncited studies that "Defendant was/is aware or should have been aware of." Doc. 1, ¶ 35. The FAC still does not allege when any studies were conducted or whether the results were available before Plaintiff's alleged injury. In her FAC, Plaintiff only adds that these "studies came to Pfizer after its initial application and FDA approval

constituting newly acquired information." Doc. 18, ¶ 36. This conclusory allegation—unsupported by any facts—does not save Plaintiff's claims. *See McCullough v. Finley*, 907 F.3d 1324, 1333 (11th Cir. 2018) (holding that "legal conclusions 'must be supported by factual allegations'" and emphasizing that "conclusory allegations" are "disentitle[d] to the presumption of truth" (quoting *Iqbal*, 556 U.S. at 679, 681)). After all, a "naked assertion[]" is not the same as a plausible allegation. *See Carruth v. Bentley*, 7:17-CV-1445-LSC, 2018 WL 1993257, at *14 (N.D. Ala. Apr. 27, 2018) (Coogler, J.).

But even crediting that allegation would not save Plaintiff's claim. As explained above, the FAC still does not allege when these studies were conducted, when their results became available, the timing of these studies in relation to Plaintiff's prescription of Lyrica, or whether these studies occurred before her alleged injury. As a result, Plaintiff has not plausibly alleged "newly-available data that [Pfizer] had or should have had *after* [Lyrica's] approval ***and before*** [Plaintiff's] injury." *McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-CV-2082-KOB, 2018 WL 1399237, at *4–5 (N.D. Ala. Mar. 20, 2018) (emphasis added) (holding that plaintiff failed to state a plausible failure-to-warn claim where "the complaint

ma[de] no allegations about the data as it existed during the relevant time period before he had [the injury]").[2]

Indeed, nearly all of Plaintiff's new allegations are not "facts" at all. They are legal assertions intended to mirror the *elements* of a non-preempted claim. For example, Plaintiff says that "[t]he CBE process was available to Defendant" and "Defendant could have made unilateral changes to the label but negligently and fraudulently failed to do so." Doc. 18, ¶ 6; *see also, e.g.*, ¶¶ 29, 45 49, 54 (alleging without factual support that Pfizer could have used the CBE regulation). As described above, no *facts* in the FAC support those naked assertions. Instead, Plaintiff tries to avoid preemption simply by alleging the elements of what would be a non-preempted failure-to-warn claim. But Rule 8 requires a plaintiff to plead facts, not to parrot a claim's legal elements. *See McCullough*, 907 F.3d at 1333 ("A plaintiff must plead more than . . . 'a formulaic recitation of the elements of a cause of action.'" (quoting *Twombly*, 550 U.S. at 555)).

Nor do Plaintiff's sole new factual "allegations" discussing the contents of a "study abstract" involving gabapentin, a different medicine, make any difference. Doc. 18, ¶ 10. To invoke the CBE process as a method to avoid preemption, Plaintiff

[2] *See also, e.g., Maze v. Bayer Healthcare Pharms. Inc.*, No. 4:18-CV-21-TAV-CHS, 2019 WL 1062387, at *3 (E.D. Tenn. Mar. 6, 2019) (granting motion to dismiss where "complaint cannot plausibly be read to contain any 'newly acquired information' . . . on the basis of which Bayer could have changed the Yaz label using the CBE process, at sometime between 2012 [the date of approval] and [plaintiff's] stroke in 2015").

must point to newly acquired information that is about the medicine at issue. *See Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1673 (2019) (explaining that the CBE regulation allows unilateral changes if "there is 'newly acquired information' about the 'evidence of a causal association' between *the drug* and a risk of harm" (emphasis added)); *see also* 21 C.F.R. § 314.70(c)(6)(iii)(A). Information about a different medicine (gabapentin) is irrelevant to whether Pfizer had newly acquired information about Lyrica, the product at issue here. *See, e.g.*, *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 664–65 (S.D.N.Y. 2017) (explaining that studies about one medicine did not constitute newly acquired information about a different medicine).

Plaintiff thus still has not plausibly alleged a non-preempted failure-to-warn claim. The Court should dismiss her warnings-based claims with prejudice.

B. Federal law preempts any design-defect claim.

As this Court recognized, Alabama does not recognize design-defect claims for prescription medicines separate from a failure-to-warn claim. Doc. 17, at 8. Because federal law preempts Plaintiff's failure-to-warn claim, *supra* at 4–7, any design-based claim likewise fails. But even if design-defect claims were independent claims under Alabama law, federal law—and FDA's approval of Lyrica's design—still would preempt Plaintiff's design-based claims here. *Cf.* Doc. 17.

The FDA has stringent regulations governing a medicine's design. *See, e.g.*, *Bruesewitz v. Wyeth Inc.*, 561 F.3d 233, 246 n.8 (3d Cir. 2009) (noting "FDA's far-more extensive control and oversight of the approval of a drug's design and alteration" than its labeling), *aff'd*, 562 U.S. 223 (2011). Most notably here, a manufacturer can *never* make major changes to a medicine's design unilaterally. *See, e.g.*, *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013); *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709, 2016 WL 1086028, at *4 (N.D. Ala. Mar. 21, 2016) (observing that, as distinguished from FDA's labeling regulations, "[n]o . . . process exists for [unilateral] changes" to a medicine's design). Instead, "were [a pharmaceutical manufacturer] to change the composition of its [medicine], the altered chemical would be a new [medicine] that would require its own NDA to be marketed in interstate commerce." *Bartlett*, 570 U.S. at 484; *see also, e.g.*, *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298–99 (6th Cir. 2015); *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166, 185–86 (S.D.N.Y. 2016).

In *Bartlett*, the Supreme Court dealt specifically with the preemption of state-law, "post-approval" design-defect claims. The Court emphasized that "[o]nce a drug—whether generic or brand-name—is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product . . . or in the specifications provided in the approved application.'" 570 U.S. at 477 (quoting 21 C.F.R. § 314.70(b)(2)(i)). That rule applies here. Once FDA

approved Lyrica, Pfizer was "prohibited from making" any major change to its design. Accordingly, a design-defect claim is preempted under *Bartlett*.

The Sixth Circuit in *Yates* found that federal law preempted design-defect claims against a brand-name medicine manufacturer. 808 F.3d at 298–300. There, the plaintiff claimed that the manufacturer should have designed its birth-control patch with .6 mg rather than .75 mg of estrogen. *Id*. at 298. As to the plaintiff's claim that the manufacturer should have reduced the dosage *after* FDA had approved the .75 mg patch, the Sixth Circuit held that federal law "clearly preempted" that claim. *Id*. This was so because, as the Supreme Court observed in *Bartlett*, "FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application.'" *Id.* (quoting 21 C.F.R. § 314.70(b)(2)(i)). "Based on the plain meaning of the regulation," the court wrote, the manufacturer "could not have altered the dosage of estrogen in [the patch] without submission to the FDA and the agency's 'approval *prior to* distribution of the product made using the change.'" *Id.* (quoting 21 C.F.R. § 314.70(b)(2)(i) (emphasis in *Yates*)). The court found it "clear" that "changing the dosage level of the active ingredient [in the patch] constitute[d] a 'major change,' such that prior FDA approval is necessary." *Id.* "Quite simply," the Sixth Circuit concluded,

"federal law prohibited defendants from decreasing the dosage of estrogen post-approval." *Id.* at 298–99.

Similarly, the *Utts* court held that federal law preempted the plaintiffs' post-approval design-defect claims. 226 F. Supp. 3d at 185–86. Echoing *Bartlett* and *Yates*, the court held that federal law preempted any claim that the manufacturers should have changed Eliquis' agency-approved design because under 21 C.F.R. § 314.70(b)(2)(i), "[t]he defendants had no ability to alter [the medicine's] composition without prior approval of the FDA."[3] *Id.* at 186.

Federal regulations prohibited Pfizer from altering Lyrica's design after FDA approval.[4] And because Pfizer could not make a major change to Lyrica's design after FDA approved it, any design-defect claim would be preempted.

[3] *See also, e.g.*, *Aston v. Johnson & Johnson*, 248 F. Supp. 3d 43, 54 (D.D.C. 2017) (federal law preempted claim that manufacturer "should have used 'other designs'" after FDA approval); *Brazil v. Janssen Research & Dev. LLC*, 196 F. Supp. 3d 1351, 1363 (N.D. Ga. 2016) ("[a]ny claim . . . that [the manufacturer] should change the formulation of [the medicine] is preempted"); *Barcal*, 2016 WL 1086028, at *3–5 (federal law preempted any claim that "would essentially require [the manufacturer] to redesign" an FDA-approved medicine); *Booker v. Johnson & Johnson*, 54 F. Supp. 3d 868, 873–75 (N.D. Ohio 2014) ("There is no dispute the [product] was approved by the FDA. . . . Therefore, it was impossible for the [manufacturers] to comply with both [their] state-law duty to alter the composition of the drug, and [their] federal-law duty not to alter an FDA-approved design.").

[4] Although Plaintiff has not clearly alleged the basis for her design-defect claim, a claim that Pfizer should have designed Lyrica differently *before* seeking FDA approval is likewise preempted. *See, e.g.*, *Yates*, 808 F.3d at 298–99; *Gustavsen v. Alcon Labs., Inc.*, 272 F. Supp. 3d 241, 255 (D. Mass. 2017); *Utts*, 226 F. Supp. 3d at 185–86; *Chambers v. Boehringer Ingelheim Pharms., Inc.*, No. 4:15-cv-00068, 2018 WL 849081, at *12–13 (M.D. Ga. Jan. 2, 2018); *Brazil*, 196 F. Supp. 3d at 1364; *Fleming v. Janssen Pharms., Inc.*, 186 F. Supp. 3d 826, 832–33 (W.D. Tenn. 2016). *But see Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187 (E.D. La. 2016).

Accordingly, the Court should dismiss Plaintiff's design-defect claim with prejudice.

II. Plaintiff's other claims remain inadequately pleaded.

The Court should dismiss Plaintiff's remaining claims under Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure.

A. Plaintiff's fraud-based claims (Counts 5–8) should be dismissed because Plaintiff has not pleaded these claims with particularity.

Plaintiff still has not met the particularity requirement of Rule 9 of the Federal Rules of Civil Procedure. *See* Fed. R. Civ. P. 9(b) (providing that a plaintiff alleging fraud "must state with particularity the circumstances constituting fraud").

As this Court recognized, the "heightened pleading standard" that applies to fraud claims "requires the plaintiff 'to plead the who, what, when, where, and how of the allegedly false statements and then allege generally that those statements were made with the requisite intent.'" Doc. 17, at 9 (quoting *Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1237 (11th Cir. 2008)); *accord Feldman v. Am. Dawn, Inc.*, 849 F.3d 1333, 1340 (11th Cir. 2017).

This Court previously dismissed Plaintiff's fraud claims because they did not "provide sufficient factual allegations regarding the alleged misrepresentations, including but not limited to facts regarding the substance of the actual alleged misrepresentations or omissions and the time or place of these misrepresentations." Doc. 17, at 9. Plaintiff's FAC fundamentally fails to include any of the facts that

this Court found missing in her original Complaint. *See generally* Doc. 18. She still has not identified any specific representation, the substance of what was stated, who said or concealed it, when and where a representation (or omission) was made, or how any representation or omission was misleading. *See Am. Dental Ass'n v. Cigna Corp.*, 605 F.3d 1283, 1291−93 (11th Cir. 2010).

Because Plaintiff has not cured the pleading deficiencies that this Court identified and for the reasons Pfizer has explained, (Doc. 10, at 9−11), this Court should dismiss Plaintiff's fraud-based claims with prejudice.

B. Plaintiff's breach of warranty claims (Counts 3, 4) remain inadequately pleaded.

Because Plaintiff still has not plausibly alleged warranty claims against Pfizer, the Court should dismiss both of those claims. As this Court previously explained, "Todd's factual allegations fail to provide information regarding the scope of the warranties alleged to have been made by Pfizer." Doc. 17, at 10. The FAC has not changed that failure. With respect to Plaintiff's express warranty claim, she has not alleged any facts suggesting the scope of any warranty that Pfizer allegedly made. *See id.* And as in her original Complaint, Plaintiff has not alleged any facts suggesting that Pfizer has ever communicated with or made any direct statements to her. *See Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003); *see also* Doc. 10, at 11–13.

As for her implied warranty claim, Plaintiff has not included any additional factual allegations to describe the scope of any implied warranty about Lyrica. And no such implied-warranty claim is even viable under Alabama law in the context of prescription medications. *See, e.g.*, *Houston v. Bayer Healthcare Pharms., Inc.*, 16 F. Supp. 3d 1341, 1347 (N.D. Ala. 2014) (dismissing implied-warranty claims); *Barnhill v. Teva Pharms. USA, Inc.*, 819 F. Supp. 2d 1254, 1263–64 (S.D. Ala. 2011); *Bodie v. Purdue Pharma Co.*, 236 F. App'x 511, 522–24 (11th Cir. 2007); Doc. 10, at 13–15.

Because Plaintiff's "factual allegations [still] fail to provide information regarding the scope of the warranties alleged to have been made by Pfizer," (Doc. 17, at 10), this Court should dismiss these claims with prejudice.

C. Plaintiff still has not identified any legal basis for her consumer protection claim (Count 9).

Nor has Plaintiff "further allege[d]"—as this Court required—"the legal basis for [her] consumer protection claims." Doc. 17, at 10. Plaintiff still has not alleged any specific consumer protection law that Pfizer allegedly violated, nor does she plead any facts to support this allegation. And because Plaintiff has provided no "indication as to the legal basis for [her] consumer protection claims," *id.*, they should be dismissed with prejudice.

CONCLUSION

The FAC does not cure the deficiencies identified in this Court's recent Opinion, (Doc. 17), and Plaintiff's claims should be dismissed with prejudice.

Respectfully submitted,

/s/ Fred M. Haston III
Fred M. Haston, III (ASB-8858-A64F)
Stanley E. Blackmon (ASB-8802-T68N)
Kaylee M. Beauchamp (ASB-7488-I17U)
Bradley Arant Boult Cummings LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203-2119
Telephone: (205) 521-8000
Facsimile: (205) 521-8800
thaston@bradley.com
sblackmon@bradley.com
kbeauchamp@bradley.com

Counsel for Pfizer Inc.

OF COUNSEL

Fred M. Haston, III (ASB-8858-A64F)
Stanley E. Blackmon (ASB-8802-T68N)
Kaylee M. Beauchamp (ASB-7488-I17U)
Bradley Arant Boult Cummings LLP
One Federal Place
1819 Fifth Avenue North
Birmingham, AL 35203-2119
Telephone: (205) 521-8000
Facsimile: (205) 521-8800
thaston@bradley.com
sblackmon@bradley.com
kbeauchamp@bradley.com

CERTIFICATE OF SERVICE

I hereby certify that on July 2, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system which will send notification of such filing to all counsel of record.

/s/ Fred M. Haston III
OF COUNSEL